K110494

510(k) Summary

as required by 21 CFR Part 807.87(h)

APR - 6 2011

Submitter:	Elaine Chang Regulatory Technical Specialist Siemens Medical Solutions USA, Inc. 2501 N. Barrington Road Hoffman Estates, IL 60192 USA
Telephone Number:	(847) 304-7516
Fax Number:	(865) 218-3019
Name / Address of Manufacturer	Siemens Medical Solutions USA, Inc. Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA
Date of Submission:	02/18/2011

Identification of the product

Device Proprietary Name:	*syngo* MBF
Common Name:	Picture Archiving and Communication System
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
SyngoCirculation Dynamic PET 1.0	Siemens Medical Solutions USA, Inc.	K083327

Device Description:

syngo MBF is a software only product intended for visualization, assessment and quantification of medical images: specifically providing quantitative blood flow measurements of PET images. The application supports dynamic Rubidium – PET and dynamic Ammonia – PET images.

The application provides visualization and measurement tools, for qualitative and quantitative visualization and assessment of the input data. It provides automatic and manual tools to orient and segment the myocardium. The software calculates measurements of myocardial blood flow, and provides tools, for the Clinician to assess these results. The user may save the results.

The application is intended for use by trained professionals. The Clinician retains the ultimate responsibility for making the pertinent assessment based on their standard practices and visual assessment of the myocardial perfusion PET images. The quantitative assessment is to be used in conjunction with traditional visual assessment of myocardial perfusion PET images for the assessment of coronary artery disease, and quantitatively by comparing to a database.

Safety and Effectiveness:

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product.

Siemens Medical Solutions USA, Inc considers that the proposed device does not introduce new safety concerns, and is substantially the same in indications for use, design, materials, energy sources and technology as the predicate devices. Siemens Medical Solutions USA, Inc believes that the *syngo* MBF software application is substantially equivalent to the predicate devices.

Indications for Use:

Siemens *syngo* MBF is a software product intended for visualization, assessment and quantification of PET images.

The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion PET images.

The product is intended for use by trained professionals. The Clinician retains the ultimate responsibility for making the pertinent assessment based on their standard practices and visual comparison of the information.

INDICATIONS FOR USE

510(k) Number (if known): K110494

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Prescription Use___X___ AND/OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Elaine Chang
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
Molecular Imaging Group
2501 North Barrington Road
HOFFMAN ESTATES IL 60192

APR - 6 2011

Re: K110494
Trade/Device Name: syngo MBF
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 29, 2011
Received: March 30, 2011

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Device
Office of In Vitro Diagnostic Device Evaluat

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